DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 3, 2015

Aptis Medical, LLC
Mr. Bryan Babb
Quality Assurance Manager
3602 Glenview Avenue
Glenview, Kentucky 40025

Re: K142569
Trade/Device Name: Aptis Medical Distal Radio Ulnar Joint Implant
Regulation Number: 21 CFR 888.3810
Regulation Name: Wrist joint ulnar (hemi-wrist) polymer prosthesis
Regulatory Class: Class II
Product Code: KXE
Dated: February 26, 2015
Received: March 2, 2015

Dear Mr. Babb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142569

Device Name

Aptis Medical Distal Radio Ulnar Joint Implant

Indications for Use *(Describe)*

The Aptis Medical Distal Radio Ulnar Joint implant is intended for replacement of the distal radioulnar joint following ulnar head resection arthroplasty:

- Replacement of the distal ulnar head for rheumatoid, degenerative, or post-traumatic arthritis presenting with the following findings:
  - Pain and weakness of the wrist joint not improved by non-operative treatment
  - Instability of the ulnar head with radiographic evidence of dislocation or erosive changes of the distal radioulnar joint
  - Failed ulnar head resection; e.g. Darrach resection
- Primary replacement after fracture of the ulnar head or neck.
- Revision following failed ulnar head arthroplasty.

This prosthesis is intended for single use only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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3. 510(k) Summary

Summary of 510(k) safety and effectiveness information upon which the substantial equivalence determination is based:

I. Submitter

Date Prepared:	April 3, 2015
Device Submitter:	Aptis Medical, LLC 3602 Glenview Ave Glenview, KY 40025
Phone:	(502)-523-6738
Contact Person:	Bryan Babb

II. Device

Device Name:	Aptis Medical Distal Radio Ulnar Joint Implant
Regulation Number:	21 CFR 888.3810
Regulation Name:	Wrist joint ulnar (hemi-wrist) polymer prosthesis
Regulatory Class:	II
Product Code:	KXE

III. Predicate Device

Predicate Device:	Aptis Medical: K040497 Distal Radio Ulnar Joint Implant K053119 Distal Radio Ulnar Joint Implant K082839 Distal Radio Ulnar Joint Implant

IV. Device Description

The Aptis Medical Distal Radio Ulnar Joint Implant system, like the predicate device includes various sizes of implants (10-30) to accommodate the anatomy of the distal ulna. The implants are made from the same materials as the predicate including; Co-Cr, UHMWPe and CPTi. Surgical instruments are also available to facilitate surgical placement of the implant. The implant allows for the replacement of the distal ulnar head.

V. Indications for Use

The Aptis Medical Distal Radio Ulnar Joint Implant is intended for replacement of the distal radioulnar joint following ulnar head resection arthroplasty:

- Replacement of the distal ulnar head for rheumatoid, degenerative, or post-traumatic arthritis presenting with the following findings:
  - Pain and weakness of the wrist joint not improved by non-operative treatment

- Instability of the ulnar head with radiographic evidence of dislocation or erosive changes of the distal radioulnar joint
- Failed ulnar head resection; e.g. Darrach resection
- Primary replacement after fracture of the ulnar head or neck.
- Revision following failed ulnar head arthroplasty.

This prosthesis is intended for single use only.

VI. Comparison of technological characteristics with the predicate device

The technological characteristics of the Aptis Medical Distal Radio Ulnar Joint Implant are very similar to the predicate device. The device consists of a plate of various sizes which is fixed to the radius and a stem of various sizes which is fixed to the ulna. The principal of operation of the device is the same as that of the predicate.

Item	*Aptis Medical*	*Aptis Medical Predicate*
Product Name	Aptis Medical Distal Radio Ulnar Joint Implant	Aptis Medical Distal Radio Ulnar Joint Implant
Use	Single use	Single use
Fixation	Stem in intramedullary canal, screw fixation to the distal radius	Stem in intramedullary canal, screw fixation to the distal radius
Constraint	Semi-constrained	Semi-constrained
Material	Co-Cr, UHMWPe, CPTi	Co-Cr, UHMWPe, CPTi
Available Sizes	10, 20, 30 Various stem sizes ranging in diameter from 4 to 6 mm	20, 30 Various stem sizes ranging in diameter from 4 to 6 mm
Indications for use	The Aptis Medical Distal Radio Ulnar Joint Implant is intended for replacement of the distal radioulnar joint following ulnar head resection arthroplasty: ● Replacement of the distal ulnar head for rheumatoid, degenerative, or post-traumatic arthritis presenting with the following findings: ● Pain and weakness of the wrist joint not improved by non-operative treatment ● Instability of the ulnar head with radiographic evidence of dislocation or erosive changes of the distal radioulnar joint ● Failed ulnar head resection;	The Aptis Medical Distal Radio Ulnar Head Implant is intended for replacement of the distal radioulnar joint following ulnar head resection arthroplasty: ● Replacement of the distal ulnar head for rheumatoid, degenerative, or post-traumatic arthritis presenting with the following findings: ● Pain and weakness of the wrist joint not improved by non-operative treatment ● Instability of the ulnar head with radiographic evidence of dislocation or erosive changes of the distal radioulnar joint ● Failed ulnar head resection;

	e.g. Darrach resection ● Primary replacement after fracture of the ulnar head or neck. ● Revision following failed ulnar head arthroplasty. This prosthesis is intended for single use only.	e.g. Darrach resection ● Primary replacement after fracture of the ulnar head or neck. ● Revision following failed ulnar head arthroplasty. This prosthesis is intended for single use only.

VII. Performance Data

Mechanical testing was performed on the subject device including; static compression, static tension, and dynamic compression tests. These tests demonstrate that the device withstood comparable loads under similar test conditions. No clinical data was submitted to support substantial equivalence.

VIII. Conclusions

The Aptis Medical Distal Radio Ulnar Joint Implant when compared to the predicate has the same indications for use, technological characteristics, and principals of operation as the predicate device. Mechanical test data demonstrates that the Aptis Medical Distal Radio Ulnar Joint Implant is as safe and effective as the predicate device. Thus the Aptis Medical Distal Radio Ulnar Joint Implant is substantially equivalent to the predicate.